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### A Quality Improvement Initiative to Manage Shingrix Vaccine Inventory in Ambulatory Clinics

Tracy Colburn

*University of New Hampshire*

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**A Quality Improvement Initiative to Manage Shingrix Vaccine Inventory in Ambulatory Clinics**

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### **Abstract**

**Background:** Inventory control practices for adult vaccines, specifically Shingrix, in ambulatory clinics are not well known or researched. This quality improvement project takes place at a small healthcare organization consisting of a hospital and thirteen ambulatory clinics in Northern New England. Seven of the thirteen clinics have the Shingrix vaccine in their inventory.

**Purpose:** The aim of this quality improvement project was multifaceted. The first matter was the establishment of a two-week PAR level at seven of the thirteen ambulatory clinics connected to the organization. The second was the design and implementation of a Shingrix vaccine management program for seven of the thirteen ambulatory clinics. This included the redistribution of inventory to prevent loss. Lastly, to create an inventory management education program for our clinical staff.

**Methods:** A rapid review of the literature was conducted using an ELCLIPS format using the Business Source Ultimate database. An informal framework of LEAN was used for this project. Three months of baseline inventory evidence was collected (pre-COVID-19) and clinic PAR levels were established from an uncertain baseline inventory and use volume estimate.

**Interventions:** A manual inventory count was conducted at each clinic. Purchase and billing information was compared to the manual count obtained at each site. Two-week PAR levels were established by comparing use tallies to a three-month use rate (pre-COVID-19). These figures were extracted from the electronic health record. An educational plan for clinic employees was developed and personnel from each of the seven clinics participated.

**Results:** Seven months following the onset of the project's implementation there were no recorded Shingrix vaccine losses and the administration of Shingrix vaccine has increased.

Significant gaps in the literature regarding inventory management and ambulatory clinics were exposed. This quality improvement project ascertained evidence demonstrating a cost savings was obtained through improved Shingrix vaccine inventory management.

**Conclusions:** There are opportunities to improve Shingrix vaccine inventory management at the organization's seven ambulatory clinics. The processes developed for this project are easily replicated and sustainable. Stakeholders within the organization have deemed this project financially beneficial to the organization and to the community: therefore, it has become a foundation for inventory management at our thirteen clinic sites.

**Keywords:** outpatient and ambulatory clinics, inventory, supply chain management, cost savings, resource stewardship, PAR levels

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**A Quality Improvement Initiative to Manage Shingrix Vaccine Inventory in Ambulatory Clinics****Introduction**

According to the American Hospital Association, the COVID-19 pandemic has challenged healthcare organizations with unprecedented and unforeseen financial implications (American Hospital Association, 2020). The National Rural Health Association reports a crucial action in response to the COVID-19 crisis any healthcare organization can take is to keep a close eye on expenses in order to maintain essential supplies (Birk, 2020). Vaccines are essential supplies. Vaccines such as Shingrix can protect against shingles, which is a very painful and costly disease. The Centers for Disease Control and Prevention (CDC) estimates one out of every three people in the United States will develop shingles because of a previous infection commonly known as chicken pox (CDC, 2019).

**Problem Description**

Herpes zoster, also known as shingles, is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes varicella (chickenpox). Reactivation of VZV that has remained dormant within dorsal root ganglia, often for decades after the patient's initial exposure to the virus in the form of varicella (chickenpox), results in herpes zoster (shingles). While usually a self-limited rash with pain, it can be far more serious as acute cases often lead to post herpetic neuralgia (PHN) and is responsible for a significant economic burden.

Shingrix, is an FDA approved vaccine for the prevention of herpes zoster (shingles) in adults aged 50 years and older. According to the manufacturer GSK, Shingrix is 90% effective at preventing the reactivation of herpes zoster in adults (GSK, 2020). At one time, the demand for the vaccine exceeded the supply and the drug was placed on long-term backorder.

In October 2019, the clinics began overcome Shingrix vaccine shortages by establishing individual GSK accounts and enrolling in the manufacturer's auto shipment program.

Establishing an account with the manufacturer ensured an allocation of 10 doses of Shingrix every three-four weeks to each clinic as opposed to 10 doses every three-four week to the organization for distribution across the seven sites. The enrollment in GSK drop shipping program resulted in a 700% increase in inventory. The vaccine was drop shipped from the manufacturer to each clinic at a cost of \$186.41 per vial. Direct shipping to each clinic continued through January 2020.

In late 2019 and early 2020, large volumes of Shingrix were discovered in the refrigerators of the seven ambulatory clinics targeted for this project amounting to thousands of dollars of inventory with some of the Shingrix vials nearing their expiration dates. Identification of this surplus in tandem with lack of inventory management resulted in this targeted area for process improvement.

There was neither a formal nor an informal process for vaccine inventory management at the ambulatory clinics. The areas of quality improvement for the clinics were to establish two-week PAR levels for the Shingrix vaccine and to create an inventory management education program for the clinical staff at the seven ambulatory clinic sites administering the Shingrix vaccine.

Initially, the scope of this project was to develop an inventory management program by establishing two-week PAR levels and for all vaccines at all thirteen ambulatory clinics. As the COVID-19 pandemic unfolded, several constraints arose. Unforeseen disruptions in healthcare



services resulted a paradigm shift in the delivery of care and in a project realignment. The focus changed to only Shingrix vaccine management.

Shingrix vaccine inventory management became this project's target because it was thought to be the most impactful vaccine in regard to inventory management issues.

Administering the Shingrix vaccine as opposed to it sitting in clinic refrigerators would benefit the organization financially and support the communities this healthcare organization serves (U.S. Department of Health & Human Services, 2020). Creating inventory management standards for the Shingrix vaccine laid a solid foundation and provided a framework for the establishment of vaccine management across all of the thirteen ambulatory clinics.

### **Available Knowledge**

There were significant gaps in the literature to describe and or support vaccine management in ambulatory clinics. However, at the onset of this project, the costs realized by this healthcare organization having Shingrix vaccine sedentary in the refrigerators equated to thousands of dollars in inventory (Appendix A). Because there was no prior tracking of inventory, previous loss estimates are only approximate as results were self-reported to this team. This team became aware of four doses of Shingrix expiring prior to the onset of this project. Additional losses and costs are innumerable to those persons afflicted with the disease shingles, some of which may last a lifetime.

Vaccines do not just prevent or minimize disease. There are both societal and organizational economic values to vaccination. The strength and vigor of a community's population is tied to the growth and sustainability of a community's healthcare system (Toumi & Ricciardi, 2015). Herpes zoster infections vacillate in severity and duration and have the

potential to inflict a significant financial blow to its victim (Wingate, Stubbs, Ahmed, Mayaka, Maneno, Ettienne, Elekwachi & Clarke-Tasker, 2018). In 2015, outpatient costs for complications such as herpetic neuralgia estimates put the incurred costs, including medical and employment loss, at \$2.4 billion dollars for American citizens (Harvey, Prosser, Rose, Ortega-Sanchez & Harpaz, 2020).

Vaccines do prevent disease. In this case, the disease shingles is 90% preventable by receiving the Shingrix vaccine two-dose series (GSK, 2020). While 30% of the American population will be afflicted with reactivation of the varicella virus (chicken pox) resulting in a herpes zoster (HZ) outbreak, 10% of those persons will go onto to develop post herpetic neuralgia (PHN). A hallmark of shingles rash is moderate to severe pain. PHN is a longer lasting pain syndrome from resulting nerve damage caused by the virus (Friesen, Chateau, Falk, Alessi-Severini & Budgen, 2017). If one were to develop a shingles infection, having had the Shingrix vaccination will minimize the disease effects (CDC, 2019).

## **Rationale**

An informal framework of LEAN methodology was implemented to drive this quality improvement project. Principles of LEAN management have been successfully employed by healthcare organizations for decades. A team from the Massachusetts Institute of Technology International Motor Vehicle Program created the term “Lean” to explain Toyota’s business process (Simon & Canacari, 2012). This method sets forth a process to identify problems, analyze the root cause of issues, develop and implement solutions and evaluate outcomes. Value is realized by eliminating waste and consequently quality, cost and timeliness of services can be improved using this methodology.

A key component of LEAN this team used is known as Gemba, a Japanese word meaning where the work occurs (Simon & Canacari, 2012). In the case of this healthcare organization, the work occurs in ambulatory clinics and that is where this team went to develop the standards for PAR levels, inventory management and to provide education. Supply chain management and operational inventory levels of Shingrix vaccine have been determined by implementing PAR levels.

PAR levels help to balance inventory needs with service needs by using ratios to determine what the inventory needs are without compromising customer service (Wilson, Hodge & Bivens 2015). The establishment of PAR levels is a well-known means of minimizing expenses. Par level management is used in healthcare to keep enough inventory on hand to meet the organization and patient needs yet not exceed a predetermined amount or PAR level thus preventing excessive inventory and expense (Walker, 2019). Seven ambulatory clinic sites have used PAR levels to demonstrate that the establishment and management of PAR levels using a formula of a two-week usage of Shingrix vaccine +1 resulted in a cost reduction.

### **Specific Aims**

The aim of this quality improvement project is multi-faceted. The first being, the establishment of two-week PAR levels at seven ambulatory clinics for Shingrix vaccine management; to implement a successful cost reduction Shingrix vaccine program in seven ambulatory clinics that included the redistribution of inventory; and to create an inventory management education program with specific training for the clinical staff. Cost reduction measures and resource stewardship are of particular importance in a COVID-19 world and has underscored the value of this project (Birk, 2020).

- There were significant limitations with obtaining baseline data because prior to the development of this project as Shingrix vaccine volumes were not previously tracked or monitored.
- Inventory sharing and redistribution has occurred because of accurate eCW inventory.
  - Shingrix inventory nearing expiration, within one month of expiration will be redistributed to another clinic for administration thus preventing expiration of product.
  - Alternatively, eCW eligible patient reports may be run enabling outreach to patients who are due or coming due for the vaccine.
- A two-week PAR level program to manage Shingrix inventory was developed by July 1, 2020.
- A clinical staff eCW training program was developed and implemented by August 1, 2020.
- Those persons who received eCW inventory training have become responsible for training the remainder of the clinical staff and new employees.

## **Methods**

### **Context**

The setting is a small healthcare organization in New England consisting of a hospital and thirteen ambulatory care clinics seven of which administer adult vaccines. At the onset of the project, five of the seven clinics had large amounts of the Shingrix vaccine in stock. Although there is not an exact figure, there were hundreds of doses in inventory. During this time, the Shingrix vaccine was nationally backordered and there were shortages across America. This

quality improvement project occurs during the pandemic, COVID-19. In order for healthcare operations to remain successful and cost efficient, waste elimination is key in supporting the success of the organization (Xu, et al., 2011). Rural hospitals and healthcare organizations have been hit particularly hard by the COVID-19 pandemic (Khullar, Bond & Schpero, 2020). These factors have only strengthened the importance of this project.

### **Cost Benefit Analysis**

Shingrix supply chain management was evaluated across the organization. There are three cost analysis associated with this quality improvement project. The first is the cost incurred by the ambulatory clinics and to the organization by having an abundance of the Shingrix vaccine sitting in refrigerators. This is inventory that has been ordered and paid for yet has not been administered therefore the clinic is unable to bill for the vaccine or the cost of the vaccines' administration. In 2019, the cost of Shingrix was \$186.41 per vial/dose. While the cost has decreased, it remains significant at \$136.50 per vial/dose.

The second aspect of cost analysis for this project became apparent within the first week of the projects implementation when the team discovered that eight vials of Shingrix would soon expire. The cost of these eight doses expiring could have resulted in a loss of \$1,491.28 to the clinic but instead resulted in a profit of \$ 2,912.00. The loss of these doses due to product expiration may also have resulted in disease. There is no way to predict the outcome of that possibility. Because this team recognized the doses were approaching the end of viability, the Shingrix vaccine was transported to another clinic and administered to patients before their expiration date.

This team was also able to redistribute 80 of 100 vials being stored in one clinic to another site for administration. In terms of cost, this equates to nearly \$15,000.00 of inventory sitting idle in a clinic refrigerator during a time when Shingrix was nationally backorder and shortages abound. Reports were run in eCW to identify patients who were due or coming due for Shingrix vaccination and concurrently, Shingrix was included in pre-visit planning for upcoming scheduled office visits. These actions thereby shrunk the Shingrix inventory of the clinic with 100 original stagnate doses to an inventory of 10 doses. The two-week PAR level for this ambulatory clinic is currently at 20 vials.

The third cost analysis is the cost of disease prevention and long-term complications to persons in the community. The CDC estimates that one out three persons in the U.S. will developed shingles and of those 10% to 18% will go on to develop post herpetic pain neuralgia (PHN) (CDC, 2019).

In 2018, outpatient disease cost estimates for non-complicated disease cases ranged from \$800 to \$1,500 per patient. For those developing PHN outpatient cases can range from \$1,425 to \$7,300 per patient. Productivity and work loss estimate for a non-complicated diseased person averages \$2,350 with total societal burden for all severity levels ranging from \$1 billion to \$1.9 billion (Wingate, et al., 2018) (Appendix A).

## **Interventions**

In order to establish PAR levels, the team determined what data would be collected. A process for data extraction was developed and implemented. The process consisted of using eCW reporting to perform a three-month look back at Shingrix administration per site- pre-COVID-19 and comparing that volume with purchasing orders for the same time period in conjunction with

using the PharmacyKeeper program to track PAR levels at each site. Again, prior to this project, Shingrix inventory, ordering and use was not tracked. This resulted in very little baseline data to facilitate the process. PAR level inspection templates were designed for use with the PharmacyKeeper program (Appendix B). Templates for vaccine ordering were designed and implemented at the seven clinics (Appendix C). Policies for Vaccine Management and Standing Orders for Shingrix administration were written by the team and approved by the organization's stakeholders (Appendix D & E). Clinic staff were educated regarding form location and use, policies were reviewed, and PAR levels were set. Vaccine ordering forms were placed on the organization's Intranet for quick and easy access. An educational program demonstrating eCW inventory use was implemented (Appendix F). Review of how to withdraw Shingrix from the eCW inventory document vaccine administration in the clinical note was conducted at seven ambulatory clinics sites (Appendix G). A standing order for Shingrix administration was also rolled out to the seven practices for use by medical assistants and nurses (Appendix H).

### **Study of Interventions**

The impact of the interventions was assessed in real time in conjunction with the organization's pharmacy purchasing department. In order to ensure PAR level adherence, the clinicians and practice managers at the seven sites will be provided with their Shingrix PAR levels. Whenever an ambulatory care clinic places a vaccine order to replenish their stock, the request is forwarded to the team for review. The team assesses several factors including if the correct ordering form was used, if the requested vaccine volume is in accordance with the established PAR level, if the current inventory in eCW is accurate and if there is a stagnant supply at one of the clinics that could be redistributed. If anything is incongruent with the recommended

process, the team will contact the ordering clinician to discuss and educate so corrections can be made. Then the ordering form is returned to the pharmacy purchasing department for processing.

## **Measures**

The processes are measured through onsite team inspections using the PharmacyKeeper program and comparing them to eCW inventory. Inventory was continually assessed via eCW to serve as back up for onsite inventory management. A vaccine manager at each site is responsible for conducting weekly inventory reconciliation between the actual inventory on hand and the eCW inventory. This ensures both accuracy of PAR levels and waste avoidance. If a Shingrix vaccine is nearing its expiration date, the team is notified. PAR levels and inventory at other clinics is evaluated to determine which ambulatory clinic is experiencing higher vaccine administration rates and redistribution of the Shingrix vaccine to the higher use clinic has occurred.

Additional ongoing assessment and evaluation will include:

- The volume of Shingrix redistribution that is occurring. This has resulted in re-evaluation of PAR levels for three ambulatory clinic sites.
- Adherence to project components based on inventory evaluation and email of Shingrix order requests from the pharmacy supply department to this team.
- Tracking of all clinical staff trained and incorporating the training into onboarding of new clinical staff.
- Quarterly updates on project status to Quality Department and Pharmacy Director.
- Monthly status updates to Practice Managers.
- Timing of implementing other vaccines into the project.



**Analysis**

The analysis of this quality improvement project is quantitative. Initially and unexpectedly, loss prevention occurred during an on-site inventory analysis. It was discovered there were eight doses of Shingrix near their expiration date. The eight doses were redistributed to another clinic and administered prior to their expiration. It is the hope of this project team to prevent Shingrix from nearing its expiration date through implementation of weekly inventory reconciliation and close evaluation of volumes. Usage reports continue to be extracted from eCW. This continues to allow the team to act quickly to redistribute vaccine from an office with low usage and stagnate inventory to an office with high usage and or a patient wait list for Shingrix vaccine. The ambulatory clinics are currently experiencing unexpected staff absenteeism because of COVID-19 and high employment turnover rates. This has resulted in much of this project oversight occurring by the team as opposed to clinical staff on site. This process is in current use. Since the initial redistribution of Shingrix there has been no Shingrix vaccine loss reported or recorded.

**Ethical Considerations**

There were no ethical considerations as this is a quality improvement project related to inventory control and education of clinical staff and not a patient population. There were no potential conflicts of interests.

**Results**

The scope of this project changed significantly because of COVID-19. Initially the range of this project was to include an inventory management program for all vaccines at the thirteen ambulatory clinics. As the COVID-19 pandemic unfolded, several constraints arose. Unforeseen disruptions in healthcare services resulted in a project realignment and the focus changed to only

that of the Shingrix vaccine management. Shingrix vaccine inventory management became the target because it was thought to be the most impactful vaccine in regard to inventory management.

The first segment of this quality improvement project was to establish a relationship with the pharmacy personnel including the Director and Buyer. This is the early development of our team. The team met weekly for several weeks with a PharmacyKeeper project developer to assist the team with our projects vision and needs including program user training and education. The PharmacyKeeper program has proven to be a useful tool for inventory management and tracking. A great deal of collaboration occurred between the project team and the staff of the ambulatory clinics. Through eCW reporting data extraction from the seven sites began. The team determined the inventory in eCW was not accurate at any of the seven clinics. After onsite inventory data was collected and purchase order information was compared two-week PAR levels were established for each of the clinics. A literature review was also conducted and revealed significant gaps in information and research to help facilitate this projects plan formation.

Our team forged ahead to the second stage and regular meetings were planned with designated clinical staff at each clinic site. On occasion the meetings occurred daily because that level of collaboration was required to solidify the foundation at each clinic site. Clinics with excessive PAR levels worked with the team to redistribute Shingrix to clinics with known higher usage. PAR levels were re-evaluated on at least a weekly basis for all seven ambulatory clinics. Eight doses of soon to expire Shingrix vaccine were discovered in a clinic and the inventory was salvaged resulting in a cost savings from loss prevention as well as a profit from administration of the vaccine.

The last stage of the project rollout mainly consisted of re-evaluation of the project's implementation and plan revisions at each clinic site. The project team held regular Zoom meetings where project information was disseminated to each of the clinics and to the organization stakeholders. Modification of PAR levels occurred in real time as not leave a clinic without necessary Shingrix vaccine for their patients or risk loss due to expiration of the product. Modification of PAR levels occurred at all sites due to a surge in office visits during the summer once COVID-19 stress began to ease.

Site inspections continue to occur regularly to ensure eCW inventory is accurate in that the numbers align with the actual inventory on hand. Education of our processes and policies transpired simultaneously with the clinical staff during the onsite inventory checks. Interventions to alter PAR levels and staff education continue at each clinic.

An unanticipated outcome occurred at one of the ambulatory clinics. The clinical staff using tools put in place by this team, took it upon themselves to run reports in eCW to identify those patients due or coming due for either a first or second Shingrix vaccination. Patient outreach occurred which often resulted in a curbside nurse visit being scheduled (Appendix J). These actions generated revenue and provided added disease protection to patients in our community. The Shingrix vaccine is billed to insurance between \$266.00 to \$ 364.00 depending on insurance type and an administration fee of \$43.00.

**Shingrix** organization bills at \$266.00 – our vaccine cost \$136.50 =

\$ 129. 50

**Admin fee**      \$ 43.00

**\$172.50 per injection**

## **Discussion**

### **Summary**

Quality improvement projects are a healthcare organization priority, and this project was and remains a team effort. While there were multiple iterations of this project, COVID-19 created the biggest obstacle and was the sole reason the team was required to pivot from a broad all-encompassing vaccine management project to that of a single aspect of PAR level inventory management for the Shingrix vaccine.

The first aim, to develop two-week PAR levels of Shingrix vaccine at seven ambulatory clinics was achieved and has been re-evaluated and revised several times at three clinics because of alternations in patient volume. One of the alterations became necessary because a provider re-located to another clinic and two alternations in volumes occurred at two other clinics because of an uptick in demand thought to be in part brought on by COVID-19 and a national promotion of vaccinations in general.

The second aim, developing and implementing a cost reduction Shingrix vaccine program at seven ambulatory clinics is thought to be successful. However, because of a previously non-existent inventory management program and very limited baseline data, assigning a number or dollar figure was not possible. We do know for certain that our supply chain management now better ensures that Shingrix vaccines are not lost due to things like temperature excursions and inventory expiration and that our volumes are in better alignment with patient need and demand.

The third aim, developing and implementing a comprehensive vaccine inventory manage program has been implemented across the seven ambulatory clinics. Education with our clinical staff along with both onsite and remote PAR level inventory management monitoring continues in conjunction with the pharmacy buyer and personnel in the clinics.

## Limitations

This quality improvement project encountered several limitations the most profound and unanticipated was that it occurred during a pandemic. Because there was a complete lack of a standard approach to inventory management there was limited baseline data available and the team was unable to with certainty calculate wasted doses or unpaid claims data.

At least two barriers arose concerning clinic staff of the seven clinics. One being the volume of staff turnover (those leaving their clinical positions) and staffing shortages and two, the attitude of some staff member's attitude regarding a change in, "the way we've always done things." This was especially challenging to address because it was important to balance enforcing behavioral expectations with the need to keep bodies to renew prescriptions, room patients and administer vaccines. There was fear that if behavior was forced to be corrected- either formally or informally, that the employee may just seek employment elsewhere. This balance was difficult but not insurmountable. It required more effort and finesse, and our time could have been better spent elsewhere.

COVID-19 proved to be a limitation in that it was difficult to use previous office visit volumes to assist in PAR level predictions (see Table 1). Additionally, the outlier clinic 3 acquired a provider and the provider's panel during this period, which skewed our estimates.

Table 1
---------

Clinic site	Office Visit Volume March 2019- October 2019	Office Visit Volume March 2020- October 2020
1 NJ	14,270	11,776
2 TA	4,756	4,023
<b>3 PS</b>	<b>2,738</b>	<b>4,023</b>
4 SE	3,648	2,817
5 SC	14,641	13,006
6 DY	10,727	9,125
7 DP	7,132	5,772

Another limitation of the project is the use of an antiquated pharmacy purchase tracking system. This made data extraction especially difficult as it was a manual process. Purchase orders and invoices are stored in folders on a public drive, in monthly folders per site and in different formats. Some of the data is available in an Excel spreadsheet while other data is the actual manufacturer invoice scanned into a folder as a PDF.

## **Conclusions**

This quality improvement project was also a process improvement project and was beneficial in terms of improving the quality of care for patients, but also generating revenue and prevented inventory loss all while working to unit our practices drawing personnel out of their silos. Shingrix management is a critical service and should not create a financial burden for ambulatory clinics. This team has shared and brought awareness to our clinical staff gaining understanding of the financial aspects of immunization, including ordering, storage administering, and documenting Shingrix vaccine so that these seven clinics can continue their mission of helping patients stay healthy while sustaining profits for the clinics.

This project is a worthwhile endeavor. Better and more efficient methods of tracking Shingrix vaccines have led to a decrease in the time required by clinical staff to figure out how to manage inventory on their own and has prevented vaccine waste. This is a sustainable and replicable project with demonstrated cost savings.

The next steps of project advancement will be to use the established framework for Shingrix management across thirteen ambulatory clinics for all inventory including vaccines for adults and children and medications. All aspects of inventory management for these clinics will

directly and indirectly enhance patient quality of life and help to sustain the strength and vigor of this small community health care system.

Sharing this project and its framework across all clinics will unify practices via inventory management education. While each clinic once ordered supplies and suffered in silence when found with either an abundance of inventory or not enough to meet the needs of the patients, we have now created a true fabric of collaboration. These silos have been breached through use of eCW and through the sharing of supplies, expenses and profits. Where once each clinic had to order a box of 10 Rotateq or Varicella, now this team and the clinics staff at each site will help redistribute and share inventory cost and profits across several sites.

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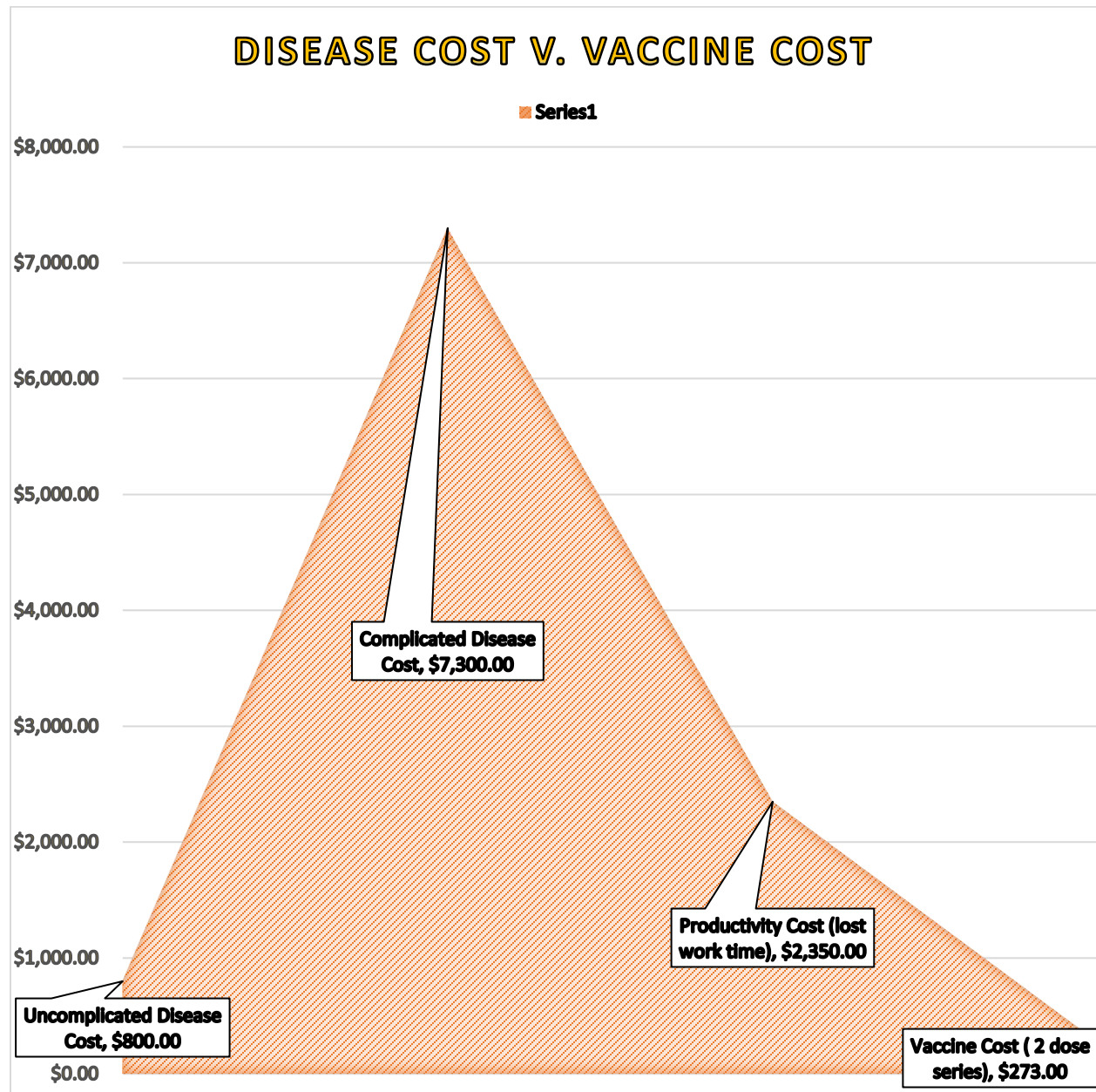
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## Appendix A

## Vaccine Cost v. Disease Cost



## Appendix B

### PharmacyKeeper Template (partial)

Dashboard Pharmacykeeper Inspection Completed/ Inspection History/ Scheduled Inspection for PAR Levels and Inventory  
**XXXX Family Practice**

#### Scheduled Inspection Details

**Location:** XXXX Family Practice

**Status:** Completed

**Scheduled Inspection Date:** 09/01/2020

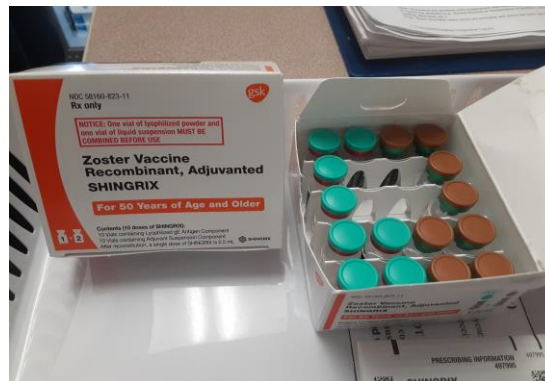
**Actual Inspection Date:** 09/14/2020

**Assigned To:** Tracy Colburn

**Performed By:** Tracy Colburn

**NOTES:** You may return excessive vaccine to pharmacy attn. Sara. I will check with other offices to see what we can re-distribute/re-locate. Thank you.

Medication/Vaccine	PAR	Amount on Hand	Return
Shingrix	2 doses	20	18 doses (see photo)



## Appendix C

## Vaccine Order Form

**ADULT VACCINE ORDER FORM**

Adult Vaccines	Alt. Names	Package Size	Quantity
Hep A	Havrix	10 per package	
Hep B	Energix B	10 per package	
Hep A & B	Twinrix	10 per package	
HPV	Gardasil 9	10 per package	
Meningococcal (A, C, W & Y)	MCV 4	5 per package	
Meningococcal Grp B	Bexsero	Individual /10 per pack	
MMR	MMRII	10 per package	
Influenza		Individual doses	
Pneumococcal 13	Prevnar 13 (Conjugate)	Individual/10 per pack	
Pneumococcal 23	Pneumovax 23 (Polysaccharide)	10 per package	
Rabies	Rabavert	Individual doses	
Shingles	Shringrix	10 per package	
Tdap	Boostrix	Individual/10 per pack	
Td	Tetanus & Diphtheria	10 per package	
Tuberculin	PPD	Vial	
OTHER			
RECV'D BY Signature:			Date:
Pharmacy Signature:			Date:

## **Appendix D**

### **Policy: Vaccine Inventory Management and Reconciliation**

#### **PURPOSE:**

This process is intended to promote and ensure that private and state vaccine and medication inventory management for both adult and children's supply is consistent, occurs on a regular basis, and that collaboration occurs amongst clinics.

#### **POLICY:**

It is essential to any medication and vaccine program that the inventory on hand is accurate and accounted for in a timely manner. Good stewardship of vaccines and medications reduce waste and resources of all clinics and ensures documentation in eCW and ImmPact is both accurate and timely. Medication and vaccine inventory and reconciliation for both private and state vaccine will occur at the end of a day or prior to the start of a day **every week**.

#### **RESPONSIBILITY:**

All clinical staff; Practice Managers are responsible to account for this being done on a weekly basis; The Director of Practice Operations will designate a clinical representative to conduct random site audits.

#### **Definitions:**

Inventory: the physical supply of medication and vaccine on hand at a point in time.

Reconciliation: the process by which one ensures all inventory is accurately accounted for and documented utilizing par levels and inventory logs.

#### **PROCEDURES:**

1. Inventory will be manually counted and recorded once per week. This process will include ensuring lot numbers and expiration dates are congruent with the actual inventory volume and set par levels are being adhered to.

- If there is an abundance of inventory and or expiration dates are coming due in the next month (or two) an attempt to re-purpose the vaccine within the organization should occur.
  - Depending on the source of the medication and vaccine, options may include:
    - An email to all Practice Managers notifying of the availability of soon to expire inventory and asking if another office could use the inventory
    - Sending it back to the Pharmacy (if non-VFC supply)
    - Contacting ImmPact Help Desk and requesting vaccine be posted on their website in hopes another practice outside of our organization can use the product ( if it is a VFC/State product)

- Inventory Reports should be run from eCW and ImmPact-if applicable. If participating with the VFC program, reports from eCW and ImmPact should be reconciled. For medications and private vaccine (adult or child) inventory should be reconciled using eCW inventory reports.

2. Reconciliation will occur minimally once per week when inventory is counted.

- Reconciliation may occur in different ways depending upon what the inventory discrepancy is.
  - Depending on the source of missing medication or vaccine- private or State, options may include:
    - Running reports in eCW and cross checking to ensure documentation is done correctly
    - Reviewing the daily schedule to identify flags

## REFERENCES:

[Vaccine Ordering and Delivery PP045 policy](#)

## **Appendix E**

### **Policy: Vaccine Ordering and Delivery**

#### **PURPOSE:**

To establish a standardized process for the ordering and delivery of vaccines from the Pharmacy to our clinics. To provide a reference tool for all clinics regarding the availability of vaccines that can and should be administered within the primary care setting.

#### **POLICY STATEMENT:**

It is the policy that all Primary Care Practices will have a vaccine inventory on site for adults and children above and beyond those vaccines supplied through the State of Maine Vaccine For Children (VFC) program. Primary Care Practices will administer most necessary and standard vaccines and Mantoux tuberculin tests or purified protein derivative (PPD) to patients in a timely, efficient and convenient manner.

#### **RESPONSIBILITY:**

It is the responsibility of all practice personnel and clinical support staff to provide care in compliance with this policy.

#### **PROCEDURE:**

1. All vaccine ordering and delivery will utilize the Pharmacy Vaccine ordering form that is available on the Approved Form section on the Intranet.
2. The ordering practice will send the completed order form via email addressed to Pharm Req.
3. This same form will also serve as verification of receipt of the order and is to be presented by the delivery person to receiving person to ensure accuracy of order, accountability for accepting the order and ensuring proper refrigeration upon arrival. The signed form is returned to the Pharmacy by the delivery person and recorded at the pharmacy.
4. Most vaccine is available to any practice location within 24 hours of ordering.
5. Clinics are expected to manage their inventories responsibly including not having excessive amounts of vaccines on site, rotating stock, monitoring expiration dates and reaching out to other practices when expiration dates are nearing to decrease the occurrence of preventable vaccine wastage.
6. Mantoux/PPD skin tests may be planted by a MA but must be read by licensed personnel such as a RN, LPN or provider.
7. Vaccine refrigerators are to be consistently monitored to maintain temperatures between 36 to 46 degrees F or 2 to 8 degrees C, freezers are to maintain temperatures between -58 to +5 degrees F or -50 to -15 degrees C.

**REFERENCES:**

[Vaccines Storage and Handling Toolkit | CDC](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

*XX Policy HW.119*

<https://intranet.hospital.com/Quality/layouts/15/start.aspx#/Approved%20Forms/Forms/AllItems.aspx>



## Appendix F

### Adding Vaccine into eCW Inventory

Open Vaccine Lot Number Inventory module in eCW → Select Facility using carot → Select New

**Lot Numbers**

Facility  Lot type Active

Find

Lot Number	Vaccine Name	Lot Type	Expiry Date	Dosage	Dosage Left	
1602284	HPV/Gardasil 9 (State Supply)	Govt(VFC)	09/26/2021	0.5	2	
1621931	HPV/Gardasil 9 (State Supply)	Govt(VFC)	01/26/2022	0.5	0	
1687291	HPV/Gardasil 9 (Private Supply)	Purchased	09/11/2022	0.5	9	
239TF	Hep B- Adult (3-dose) (Private supply)	Purchased	06/04/2022	1.0	0	
2774D	Tdap (State Supply)	Govt(VFC)	03/09/2021	0.5	0	
279843		Unknown	06/30/2021	0.5	0	
2KK23	Tdap (Private)	Purchased	09/19/2022	0.5	0	
2KK23	Tdap (Private)	Purchased	09/19/2022	0.5	-1	
25M24	Influenza (FluLaval) 0.5 mL (State supply)	Govt(VFC)	06/30/2021	0.5	0	
33AT7	Tdap (Private)	Purchased	10/07/2022	0.5	43	
373H3	Influenza (Fluarix) 0.5 ML (Private Supply)	Purchased	06/30/2021	0.5	3	
3E279	Shingrix (private supply)	Purchased	03/19/2022	0.5	0	
3HR79	Hep A, ped/adol (Private Supply)	Purchased	09/16/2021	0.5	-1	
3HR79	Hep A, ped/adol (Private Supply)	Purchased	09/16/2021	0.5	6	
3Y7NL	Twinrix (Hep A-Hep B)	Purchased	05/24/2022	1.0	7	
47CX9	Pediarix (DTaP-HepB-IPV) (State Supplied)	Govt(VFC)	05/29/2022	0.5	10	
494PR	Shingrix (private supply)	Purchased	09/13/2021	0.5	0	
4F472	Hep B- Adult (3-dose) (Private supply)	Purchased	11/06/2022	1.0	20	

Date Inventory Entered 11/10/2020

Manually enter information in boxes and select OK.

**Lot Numbers**

Lot Numbers ▸ Add/Edit Lot Numbers

Lot Number: 11111

Manufacturer: Abbott Laboratories

Expiry Date: 11/11/2020

VIS Date: 01/01/2020

Dosage: 0.5 mg

No. of Doses: 10 Doses Remaining: 10

Route of Admin: Intramuscular

Imm/Th. Inj: Immunization

Facility: [Search Box]

Lot Type: Privately Purchased (Practice)

NDC Code: 58160-823-11

Immunization: Shingrix (private supply)

Transactions

Entered Date	Code	No. of Doses	Comments	Entered by
--------------	------	--------------	----------	------------

Scan Barcode OK Cancel

Shingrix has been successfully added to eCW Inventory

**Lot Numbers**

Facility: [Search Box] Lot type: Active

Find: [Search Box]

Include Lots with zero doses Left: ☒

Settings New Export To Excel Reconcile

Lot Number	Vaccine Name	Lot Type	Expiry Date	Dosage	Dosage Left	
4F99G	Tdap (State Supply)	Govt(VFC)	08/19/2022	0.5	-4	
4ME42	Shingrix (private supply)	Purchased	11/14/2021	0.5	10	
52S9R	Influenza (Fluarix) 0.5 ML (Private Supply)	Purchased	06/30/2021	0.5	87	
53F43	Kinrix (DTaP-IPV) (private supply)	Purchased	10/17/2020	0.5	0	
5552S	Shingrix (private supply)	Purchased	02/26/2022	0.5	0	
5E43J	Tdap (State Supply)	Govt(VFC)	08/30/2022	0.5	30	

The process is the same for all vaccines.

## Appendix G

### Documentation of Administration

In the Progress Note

#### Immunizations/Injections – Order/Administer Immunizations

- Click the “Immunizations” or “Therapeutic Injections” link from the progress note, to open the “Immunizations” window.

**Plan:**

Treatment:

Procedures: ▼

**Immunizations:**

**Therapeutic Injections:**

- Provider will click on the “Add” button to add an immunization.

Immunizations ( [ ] Y, M 12/13/1960 )

T. Injections Immunization Immunization Schedule Flu schedule

Imm Verified Add

S ▼	Name ▲	Dose	Date ▼	Given By	Location	Lot Number	
No Records Found							

2. Search for and select the immunization using the “Find” field.
3. Select the diagnosis for which the immunization is being administered.
4. The status will automatically populate as pending until the MA administers the vaccination.
5. The Medical Assistant documents the Status as Administered, including Given By, and Location given.
6. Click on the ellipsis [...] next to the Lot Number.

The screenshot displays the 'Immunization Details' form for a patient named 'Conrad, Jeff' (55 Y, M, 12/13/1960). The form is divided into several sections:

- Left Panel (Callout 2):** Contains a search bar with 'dt' entered and a list of immunization types: DT, DTap, DTap1, and DTP. DTap is currently selected.
- Top Right (Callout 3):** The 'Assessment(s)' section, which includes a 'Select All' checkbox and a list of medical conditions: E11.9 Type 2 diabetes me..., J20.2 Acute bronchitis du..., and I10 Essential (primary) hy....
- Main Form Fields:**
  - DTap Section:** Includes a checkbox for 'Vaccination given in the past'.
  - Visit Date:** 2016-04-04 F/U (Callout 4).
  - Dose:** A dropdown menu.
  - Dose Number:** 0 (Callout 5).
  - Lot Number:** A text field with an ellipsis icon and a 'VFC' checkbox.
  - Route:** A dropdown menu.
  - Location:** A dropdown menu.
  - Exp. Date:** A date field.
  - VIS Given Date:** 04/05/2016.
  - Status:** Pending (Callout 4).
  - Reason:** A text field with a 'Clr' button.
  - Given By:** A search field with a 'Me' button and a 'Clr' button.
  - Given Date/Time:** 04/04/2016 03:22 PM.
  - Manufacturer:** A text field.
  - VFC:** A dropdown menu.
  - Date on VIS:** A date field.
- Right Panel:** Contains a 'Comments' section with a text area and checkboxes for 'Decrement the dose', 'Billable', and 'Counseling'.

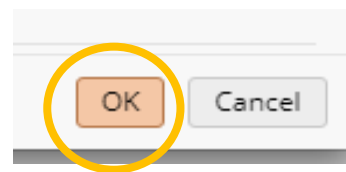
6. Select the lot number, administered and OK.

**Lot Numbers**

Facility   Lot type  Active  ☒ Include Lots with zero doses Left

Find

Lot Number	Vaccine Name	Lot Type	Expiry Date	Dosage	Dosage Left	
1602284	HPV/Gardasil 9 (State Supply)	Govt(VFC)	09/26/2021	0.5	2	<input type="button" value="Edit"/> <input type="button" value="Delete"/>



7. Once all the fields have been documented:
- Click "Save and New" if another immunization needs to be given.
  - Click "OK" if the immunization documentation is complete.

**Immunization Details** (55 Y. M. 12/13/1960)

Active  dtap

**DTap**

☐ Vaccination given in the past

Visit Date: 2016-04-04 F/U

Dose: .5 milliliters

Dose Number: 1

Lot Number: 12334567909 ☐ VFC

Route: Intramuscular

Location: Left Thigh

Exp. Date: 04/04/2017

VIS Given Date: 04/05/2016

Status: Administered

Reason:

Given By: Willis,  Me

Given Date/Time: 04/04/2016 03:34 PM

Manufacturer: Abbott Laboratories

VFC:

Date on VIS: 04/30/2016

**Assessment(s)**

☐ Select All

☒ E11.9 Type 2 diabetes me...

☐ J20.2 Acute bronchitis du...

☐ I10 Essential (primary) hy...

**Comments**

☒ Decrement the dose

☒ Billable

☐ Counseling

8. The immunization is saved and appears on the Immunization window.

The screenshot shows a software window titled "Immunizations" for a patient named "55 Y, M 12/13/1960". The window has four tabs: "T. Injections", "Immunization", "Immunization Schedule", and "Flu schedule". The "Immunization" tab is selected. In the top right corner, there is a checkbox labeled "Imm Verified" and an "Add" button. Below this is a table with the following columns: "S", "Name", "Dose", "Date", "Given By", "Location", and "Lot Number". The table contains one row with the following data: "DTap", ".5 mL", "04/04/2016", a blue selection bar, "Left Thigh", and "12334567909". At the bottom left, there are buttons for "Print", "Fax", and "Print Form". At the bottom right, it says "Total Counts : 1" followed by "Prev", "Page 1 of 1", "Next", and a "Close" button.

S	Name	Dose	Date	Given By	Location	Lot Number
	DTap	.5 mL	04/04/2016		Left Thigh	12334567909

Note: Provider selects the Immunization which is then in pending status until the clinical staff administers and populates all the other pertinent fields.

9. If patient or patient family declines the immunization, then follow the steps.
  - a. Select the status to "Not-Administered"

## Appendix H

### Shingrix Standing Order

#### PURPOSE:

To reduce morbidity and mortality from herpes zoster infection (shingles) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

#### POLICY:

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

#### RESPONSIBILITY:

It is the responsibility of ALL practice providers and clinical support staff to provide care in compliance with this policy.

#### PROCEDURE:

1. Assess adults age 50 Years and older for need of vaccination against herpes zoster virus infection. The CDC recommends **two Intramuscular doses of Shingrix 2 to 6 months apart**. It is preferred over Zostavax and should be given to any patient 50 years of age or older. Shingrix is appropriate for administration:
  - Whether or not they report a prior episode of herpes zoster
  - Whether or not they report a prior dose of Zostavax
  - For those with chronic medical conditions (e.g., chronic renal failure, diabetes mellitus, rheumatoid arthritis, chronic pulmonary disease), unless a contraindication or precaution exists.
  - Similar to Zostavax, Shingrix may be used for adults who:
    - Are taking low-dose immunosuppressive therapy as this *may decrease the efficacy*
    - Are anticipating immunosuppression
    - Have recovered from an immunocompromising illness
    - Are receiving other adult vaccines in the same doctor's visit, including those routinely recommended for adults age 50 years and older, such as influenza and pneumococcal vaccines
    - Have had a prior Zostavax > 8 weeks prior.
2. Screen for Caution & Precautions

#### Caution

  - Do not administer to anyone with an active herpes zoster outbreak
  - Do not administer to anyone who has received the live Zostavax within the last 8 weeks

**Precautions**

- Moderate or severe acute illness with or without fever
  - Live vaccine, including Zostavax in the last 8 weeks
3. Vaccine Information Statements (VIS)
    - Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language.
  4. Prepare to Administer Vaccine and refer to XX Policy:  
PP009 XX Standing Orders Med Vaccine Administration for Patients One Month and Older.  
PP010 XX Standing Orders Medical Management of Vaccine Reactions in Patients one month or Older.  
HW115 Environment of Care Proper Disposal of Sharps Needles.  
HW331 Infection Control Hand Hygiene Compliance.  
HW119 Environment of Care Medications, Specimen and Reagent Storage
  5. Administer Shingrix/Zoster Vaccine Recombinant Adjuvant
  6. Document each patient's vaccine administration information and that a VIS was provided in the electronic medical record.
  7. Be Prepared to Manage Medical Emergencies.  
To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

**QUALITY IMPROVEMENT:**

Standing Orders are reviewed at least annually by XX lead providers for evidence-based practice.

**REFERENCES:**

Immunization Action Coalition, Saint Paul, Minnesota. [www.immunize.org](http://www.immunize.org)  
[www.vaccineinformation.org](http://www.vaccineinformation.org)



**Appendix I****Algorithm for Shingrix Curb-Side Nurse Visits****Booking in-Vehicle Nurse Visits for Shingrix Injection**